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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,505	11/23/1999	ROBERT M. GOODMAN	16518.076	3907

7590

05/14/2003

Arnold & Porter
Attn: IP Docketing Dept., 1126B
555 Twelfth Street, NW
Washington, DC 20004-1206

EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/14/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/447,505

Applicant(s)

GOODMAN ET AL.

Examiner

Cynthia Collins

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-61 and 71-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 45-50, 54, 56-61 is/are allowed.
- 6) ☒ Claim(s) 51-53, 55, 71-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed March 3, 2003, paper no. 13, has been entered.

The Terminal Disclaimer filed March 3, 2003, paper no. 14, has been entered.

Claims 62-70 are cancelled.

Claims 45, 46, 47, 49, 54 and 55 are newly amended.

Claims 71-73 are newly added.

Claims 45-61 and 71-73 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 51-53 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for dicotyledonous plant cells comprising and expressing an isolated nucleic acid coding for a mammalian peptide, does not reasonably provide enablement for other types of plant cells comprising and expressing an isolated nucleic acid coding for a mammalian peptide, or for plant cells comprising and expressing an isolated nucleic acid coding for a mammalian peptide that has a physiological effect upon ingestion by a mammal, for the reasons of record set forth in the office action mailed December 3, 2002.

Applicants' arguments filed March 3, 2003, have been fully considered but they are not persuasive.

Applicants argue that the amendment of claims 45-47 and 49 to recite that the plant cells are dicotyledonous should overcome the rejection.

The amendment of claims 45-47 and 49 to recite that the plant cells are dicotyledonous addresses the enablement of claims 45-50, and the rejection of claims 45-50 has been withdrawn. The amendment does not, however, address the enablement of claims 51-53, because recitation that the cells are dicotyledonous does not address the unpredictability of and lack of guidance for expressing a gene coding for a mammalian peptide in a plant cell in such a way that the expressed peptide would have a physiological effect upon ingestion by a mammal.

Claims 71 and 73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for dicotyledonous plant cells that express a mammalian peptide, does not reasonably provide enablement for dicotyledonous plant cells that express a mammalian peptide linked to a transit peptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to dicotyledonous plant cells that comprising a first expression cassette further comprising a nucleic acid sequence encoding any transit peptide, and to dicotyledonous plant cells that express any mammalian peptide linked to any transit peptide.

The specification discloses only the transformation of tobacco to produce plant cells comprising and expressing an isolated nucleic acid coding for murine gamma interferon (pages 15-16). The specification does not disclose the transformation of dicotyledonous plant cells using any particular nucleic acid sequence encoding a transit peptide.

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Guidance for making and using the claimed invention is necessary because the effect of any particular transit peptide on the peptide to which it is linked is unpredictable. Even functionally equivalent transit peptides can have different effects on the translocation of structurally equivalent peptides to which they are linked. For example, Clausmeyer et al. (J Biol Chem. 1993 Jul 5;268(19):13869-76) teach that exchanging functionally equivalent transit peptides between four different hydrophilic nuclear encoded plastid proteins can affect the rate of protein translocation and the routing of the protein to the thylakoid lumen (page 13871 column 2 last paragraph through page 13873 first paragraph). Clausmeyer et al. conclude that the mature forms of these luminal proteins contain information that is both essential for membrane translocation and codependent on information that resides in their cognate transit peptides (page 13875 paragraph spanning columns 1 and 2). The instant specification provides no guidance with respect to which particular transit peptides to link to which particular mammalian peptides in order to achieve a useful effect upon expression of the mammalian peptide in a dicotyledonous plant cell.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would have required undue experimentation for one skilled in the art to determine the appropriate transit peptide to link to a particular mammalian peptide.

Claim 52, and claim 53 dependent thereon, remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "physiological effect", for the reasons of record set forth in the office action mailed December 3, 2002.

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Claim 53 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “regulation of digestive function”, for the reasons of record set forth in the office action mailed December 3, 2002.

Applicants’ arguments filed March 3, 2003, have been fully considered but they are not persuasive.

Applicants argue that the meaning of “physiological effect” and “regulation of digestive function” are clear to one of ordinary skill in the art when read in light of the specification. Applicant points to page 9 of the specification which discloses that the mammalian protein product “can have a physiological effect on ingestion” and “could include proteins involved in the regulation of digestion or the like”. Applicants further argue that breadth of a claim is not to be equated with indefiniteness (reply pages 3-4).

The Examiner maintains that the recitation of “physiological effect” and “regulation of digestive function” in the rejected claims is indefinite. The references in the disclosure to the mammalian protein having “a physiological effect on ingestion” and being “involved in the regulation of digestion or the like” do not clarify the metes and bounds of “physiological effect” or “regulation of digestive function” in the claims because they do not indicate which aspects of mammalian physiology may be affected by the ingestion of a peptide, and because they do not indicate which aspects of digestive function may be regulated. The indefiniteness of the claims does not reside in their breadth per se, but in their failure to communicate what they encompass and what they do not encompass.

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Claim 72, and claim 55 dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 72 is indefinite in the recitation of "an integrated sequence". The nature of the integrated sequence is unclear, as many different types of sequences could be "integrated" into a plant's genome, such as viral sequences or microbial sequences or recombinant DNA sequences, transposons or non-coding sequences.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Remarks

Claims 51-53, 55 and 71-73 are rejected.

Claims 45-50, 54 and 56-61 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

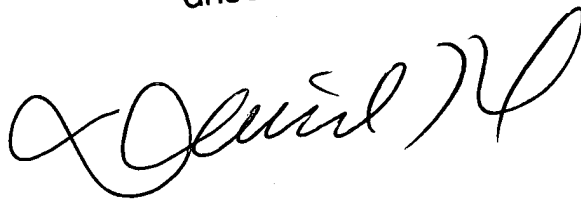
The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
May 7, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180/1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the printed name and title.